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D. Remarks

Reconsideration and allowance in view of the amendments made and comments which follow are respectfully requested.

Claims 1-60 are pending in this application. Claims 1, 12, 20, 31, 50, 58-60 are being amended.

In the Office Action dated January 15, 2003, in response to applicant's Amendment dated December 4, 2002, which stated that the instant invention is directed to prevent or reverse arrhythmias of many different causes and the Ben-Haim et al. device is directed to improve cardiac failure, hence Ben-Haim et al. fails to disclose the methods of claims 1, 20 and 39 that remodel the gap junctions, induce ion channel remodeling, and alter the refractory period, the Examiner stated that these distinctions are not recited as elements in the rejected claims (s). The Examiner stated that, although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims, and that the rejections of claims 1-60 are deemed proper.

In response, applicant has amended all independent claims to recite "prevent or reverse arrhythmias." Support for this language may be found on at least page 5 line 5; page 41, lines 13; and page 42, lines 12-15 of the application as filed.

In response to applicant's statement that Ben-Haim et al. fail to teach or suggest any aspect of remodeling gap junctions, altering the refractory period in the heart, or inducing ion

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channel remodeling.

The Examiner stated that in Paper No. 17-paragraph 3, pertinent passages from US 6363279 to Ben Haim et al. are cited indicating disclosure related to remodeling gap junctions, altering the refractory period in the heart, and inducing ion channel remodeling, and that these citations are repeated below:

The Examiner stated that Ben-Haim et al. teach a method of modifying the force of contraction of a heart by applying a non-excitatory electrical field ultimately modifying the action potentials, the ionic pumps and the channels of the heart (c 2,1 6 - c 3, 1 32).

The Examiner stated that this invention focuses on controlling the heart by modifying the channels that connect the heart; the channels are read to include gap junction channels (c 2, 1 6 - c 3, 1 32). The Examiner stated that according the Ben-Haim et al., these channels of the heart are modified by electrical stimulation (c 27, 11 12-27; c 27, 11 52-57; c 31, 11 1-5). The Examiner stated that while Ben-Haim addresses the controlling the channels of the heart, the gap junction channels are not specifically mentioned. The Examiner stated that it is, however, inherent that Ben-Haim et al. invention controls the gap junction channels as they are an essential component of the heart conduction system as noted in the art made of record (Winslow et al. (US 5947899), c5, 1 28-c 6, 1 3 and c 6, 11 33-53).

The Examiner stated that, in Ben-Haim et al., refractory periods are modified by electrical stimulation (c 8, 11 3-5; c

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8, 1 66 - c 9, 13; c 9, 11 15-19; c 17, 11 26-35; c 17, 11 45-46; c 31, 11 26-31; c 47, 11 37-45).

The Examiner stated that, in Ben-Haim et al., ion channels are modified by electrical stimulation (c26, 1 62 - c 27, 1 27; c 27; 11 43-57; c 31, 11 1-5).

The Examiner stated that, in Ben-Haim et al., changes in the heart occur over time as the heart is remodeled (c 9, 11 51-55; c 38, 1 48 - c 39, 1 10).

The Examiner stated that the rejections of claims 1-60 are deemed proper.

The Examiner stated that, based on the reasons of record and discussion in the Office Action, the rejections of record are deemed proper and stand.

In particular, the Examiner stated that claims 1, 9-11, 20, 28-30, 39 and 47-49 stand rejected under 35 U.S.C. 102(e) as being allegedly anticipated by Ben-Haim et al. (US 6363279) for the reasons of record and the discussion in paragraphs 2-3 of the Office Action.

The Examiner stated that claims 2, 5, 12, 13, 15, 21, 24, 31, 32, 34, 40, 43, 50, 51, 53 and 58-60 stand rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over Ben-Haim et al. (US 6363279) in view of Edwards et al. (US 5681308) for the reasons of record and the discussion in paragraphs 2-3 the Office Action.

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The Examiner stated that claims 3, 4, 14, 17-19, 22, 23, 33, 36-38, 41, 42, 52 and 55-57 stand rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over Ben-Haim et al. (US 6363279) and Edwards et al. (5681308) in view of Dahl et al. (US 5203348) for the reasons of record and the discussion in paragraphs 2-3 of the Office Action.

The Examiner stated that claims 7, 8, 26, 27, 45 and 46 stand rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over Ben-Haim et al. (US 6363279) in view of Dahl et al. (US 5203348) for the reasons of record and the discussion in paragraphs 2-3 of the Office Action.

The Examiner stated that claims 6, 16, 25, 35, 44 and 54 stand rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over Ben-Haim et al. (US 6363279) and Edwards, et al. (US 5681308) in view of Ideker (US 5873896) for the reasons of record and discussion in paragraph 2-3 of the Office Action.

Applicant will address the rejections based on the Ben-Haim et al. U.S. Patent No. 6,363,279 particularly those rejections of anticipation of independent method claims 1, 20 and 39. The Ben-Haim reference relates to a device which applies an electrical field to the heart. Ben-Haim et al. state that their device modified the plateau currents, resulting what is claimed to be an increase in force of contraction. However, this reference does not contain any teaching or disclosure, explicitly or inherently, for causing the heart to be excited and activated, resulting in remodeling gap junctions, inducing ion channel remodeling or altering the effective refractory

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period to prevent or reverse arrhythmias.

The Examiner has cited column 2, line 6-column 3, and lines 32 of the Ben-Haim reference to allegedly show that Ben-Haim modifies the action potential, ionic pumps and channels of the heart. The Examiner further states that the "channels" are read to include "gap junction channels."

Applicant respectfully disagrees with the Examiner's statement that "channels" include "gap junction channels" or "gap junctions." An ion channel merely connects the interior of a cell to the exterior of the same cell. A gap junction is not an ion channel, but is a specialized connection that connects the interior of one cell to the interior of another cell. The transmembrane channels are referred to as ion channels, whereas the gap junctions are referred to as connexions. When Ben-Haim uses the term channels, he is not referring to gap junctions, but instead is referring to voltage gate channels. The Ben-Haim reference does not explicitly disclose any remodeling of gap junctions.

Furthermore, Ben-Haim does not inherently remodel gap junctions. If one skilled in the art followed the disclosure and direction provided by Ben-Haim to change the ion channels, this change would be done without also remodeling the gap junctions. Accordingly, Ben-Haim does not inherently remodel gap junctions because modification of gap junctions would not necessarily occur when following the Ben-Haim disclosure to change ion channels.

The Examiner stated that "the Ben-Haim invention controls the gap junction channels," but does not state that the Ben-Haim

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reference teaches remodeling gap junctions. As stated above Ben-Haim does disclose remodeling gap junctions either expressly or inherently. Claims 1 and 12 recite that gap junctions are remodeled thus distinguishing them over Ben Haim. Accordingly, applicant believes that claims 1 and 12 are patentable over Ben-Haim.

The Examiner also stated that changes in the heart occur over time as the heart is remodeled and cites the Ben-Haim reference in column 9, lines 51-55 and column 38, line 48-column 39, line 10. These pages only state that by using electrical fields, one can change the muscle mass of the heart over time. However, changes to the muscle mass do not necessarily result in remodeling gap junctions, altering the refractory period in the heart, or inducing ion channel remodeling. Claims 20, 43, and 59 recite that the refractory period is altered, and claims 39, 50, and 60 recite that the ion channel is remodeled. None of this is taught by or inherently results from Ben-Haim.

The Examiner further stated that in Ben-Haim refractory periods and ion channels are modified by electrical stimulation. Ben-Haim, however, never discloses explicitly or inherently that ion channels remodeling is induced, or that refractory periods are altered by his electrical stimulation. While Ben-Haim in col. 26, line 62 et seq. mentions that electrical stimulation can change the movement of ion channels, such effect occurs only when the electrical stimulation continues to be applied, but the effect ceases when electrical stimulation ceases. In contrast, applicant's claims 39, 50, and 60 recite that the ion channels are remodeled, such that when electrical stimulation is applied,

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the ion channels are remodeled and remain in their remodeled state even after electrical stimulation is removed.

Similarly, claims 20, 43 and 59 recite that the refractory period is altered, such that when electrical stimulation period is altered and remains altered electrical stimulation is removed. In Ben-Haim, any change in refractory period is lost when the electrical stimulation ceases.

The presently claimed invention of claims 1, 20 and 39 provides an electrical stimulus to the heart that excites the heart and results in altered activation, which must occur for the downstream changes to occur in remodeling gap junction, inducing ion channel remodeling or altering the effective refractory period. While the objective of the Ben-Haim et al. device is to improve cardiac failure, the methods of the presently claimed invention are to prevent or reverse arrhythmias of many causes (by remodeling gap junctions, inducing ion channel remodeling or altering the effective refractory period), not just causes associated with congestive failure. For the foregoing reasons, applicant urges that Ben-Haim et al. fail to disclose, explicitly or inherently, the methods of claims 1, 20 and 39.

The other rejections are based on the Ben-Haim et al. reference in combination with at least one other reference, and rely on the Ben-Haim et al. reference as a primary reference. However, as discussed above, the Ben-Haim et al. reference fails to teach or suggest any aspect of remodeling gap junctions, altering the refractory period in the heart, or inducing ion channel remodeling to prevent or reverse arrhythmias. The other references also fail to remedy the

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deficiencies of Ben-Haim in this respect. Therefore, these proposed combinations necessarily fail to teach or suggest the claims against which they were cited. Moreover, applicant urges that there is no teaching or suggestion in the prior art or otherwise of anything that would motivate one of ordinary skill in the art to combine the references as proposed by the Examiner.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invites the Examiner to telephone them at the number provided below.

No fee is deemed necessary in connection with the filing of this Response. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

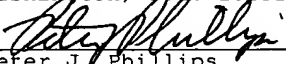
Respectfully submitted,



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